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LUTON & DUNSTABLE UNIVERSITY HOSPITAL

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Guidelines for the prescribing of specialist infant formula in primary care:

Luton and Bedfordshire

September 2017

This document is a revised edition written and agreed by Paediatricians, Paediatric Dietitians, GPs and Medicine Optimisation Teams within Luton and Bedfordshire clinical commissioning groups.

Ratified by: Bedfordshire and Luton Joint prescribing committee 20th September 2017
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Introduction:

Whilst these guidelines are for specialist infant formula, breast milk is the optimal milk for infants. Breastfeeding should be promoted and encouraged where possible.

This guideline aims to provide information to GP's and Health Visitors on the use of prescribable infant formulae. It provides guidance on initial and on-going prescribing and when to discontinue prescribing.

The guideline covers formula to prescribe from birth to 1 year of age. Some conditions may require formula to be prescribed beyond this age and this will be referenced under 'GP Review Criteria'.

Specific exceptions: If all nutrition is received by a feeding tube e.g. NG/NJ/PEG for clinical reasons (such as an unsafe swallow), a dietitian will recommend a prescription for the appropriate monthly amount and type of formula. A dietitian may calculate a different volume or suggest the use of a formula outside these guidelines based on individual need. The specific need and clinical rationale will be included with the feed prescription request.

Volumes of feed to prescribe infants:

Please use the guide below to estimate quantity of formula to prescribe. Volumes stated are the maximum that are required for an average child (on the 50th percentile for weight); however, those under the care of a dietitian may require more or less formula. Over prescribing can occur if infants are being overfed. If you suspect an infant is being overfed or a parent requires support on responsive feeding refer to the health visiting team for assessment.

Initially prescribe a 1 week trial of 2-3 x 400g tins or 1 x 900g tin;
to test tolerance and symptom management

Age of child	Number of tins for 28 days
Under 6 months	10 x 400g OR 9 x 450g tins OR 5 x 900g tins
Between 6 – 12 months	7 x 400g tins OR 6x 450g tins
Over 1 year	7x 400g OR 6x 450g tins OR other as stated on prescription request from paediatric dietitian

Summary of Guidelines for the Prescribing of Specialist Infant formula's in Primary Care June 2017						
Diagnosis	**Guidance**	**Age range**	**Formula**	**Vol. < 6mths for 28 days**	**Vol. > 6mths for 28 days**	**Review criteria**
Cow's Milk Protein Allergy (CMPA) (page 3&4)	**First Line** EHF to be used first line if CMPA suspected.	**Birth to 2 years**	**1st line primary care** **Similac Alimentum** (Abbott Nutrition) *Casein based* *Lactose free*	**10 x 400g**	**7x 400g**	Children prescribed any specialist infant formulae should be **reviewed every 6 months.** **Prescribe until 2 yrs of age** or, until age-appropriate alternative milk is advised/child tolerates cow's milk. Children with **multiple allergies** may require prescribed **specialist infant formula up to 2 yrs of age**.
	Second Line EHF to be used if first line not accepted on the basis of taste.	**Birth to 2 years**	**Althera** (SMA Nutrition) *Whey based.* *Contains lactose*	**9 x 450g**	**6 x 450g**	
	Amino Acid based formula Preferably started in secondary care for multiple allergies or IgE mediated reactions.	**Birth to 2 years**	**1st line primary care** **Alfamino** (SMA Nutrition) (h)(v)	**10x 400g**	**7x400g**	
			+ If commenced in hospital use first line **+Neocate LCP** (Nutricia) (h)(v) OR **Puramino** (Mead Johnson) (h)			
Pre-term (page 5)	**Specialist formula.** Only start in **secondary care**	**Birth to 3-6 months corrected age**	**Nutriprem 2 powder** **(**Cow & Gate)	**5 x 900g**	**n/a**	Do not issue liquid formulations as no clinical benefit.
			SMA Pro Gold Prem 2 (SMA Nutrition)	**10 x 400g**	**n/a**	
Faltering Growth (page 6)	**Specialist** High energy formula. Only start in **secondary or specialist care**	**Birth to 1 year** Up to 18 months of age or 8kgs body weight.	**Infatrini** (Nutricia) (h)	**Individual basis**	**Individual basis**	Review recent assessment report from paediatrician or paediatric Dietitian.
			SMA Pro High Energy (SMA Nutrition)			
			Similac High Energy (Abbott Nutrition) (h)(v)			
Note: The guidelines are intended for use in primary care, if clinically indicated an alternative product may be requested by secondary or specialist care. The clinical rationale will be stated in written correspondence.						

KEY	(v) suitable for vegetarians ((h) halal approved (ve) suitable for vegans.
	Use as first line extensively hydrolysed formula (EHF).
	Use as second line extensively hydrolysed formula (EHF) alternative based on taste preference.
	Preferably started in secondary or specialist services. If started in primary care, refer patient to acute service for assessment with paediatrician and specialist dietetic support

Cow's milk protein allergy (CMPA)

DIAGNOSIS:

- Cow's milk protein allergy (CMPA) suspected after taking an allergy focused history
- Lactose free formulas are **not suitable** for treating CMPA as they contain cow's milk protein.
- Refer to NICE guideline CG116 'Food Allergy in Children and Young People' (Feb 2011) and 'MAP guidelines (2013) for guidance on managing allergy in primary care'. See supporting documents page 7.

Mild to Moderate non IgE Mediated Symptoms	IgE Mediated Symptoms
Mostly **2-72 hours after ingestion** of Cow's milk protein. One or often more of these signs or symptoms: • **Gastrointestinal** - colic, reflux (GORD), vomiting, food refusal or aversion, loose/frequent stools, constipation especially soft stools with excessive straining, blood mucous in stools in a well infant. • **Respiratory** -"catarrhal airway signs". • **Skin**- significant atopic eczema, pruritus, erythema.	Mostly within **minutes of ingestion or up to 2 hours** of exposure to cow's milk. One or often more of these signs or symptoms: • **Anaphylaxis.** • **Gastrointestinal** - vomiting, diarrhoea, abdominal pain/colic. • **Respiratory-** acute rhinitis and/or conjunctivitis. • **Skin-** acute pruritus, erythema, urticarial, angioedema or acute "flaring" of atopic eczema.

TREATMENT SUMMARY:

Once treatment is commenced, it may take up to **4-6 weeks for symptoms to resolve.**

Breast fed infants:

- Breast fed infants should be trialled with a maternal milk free diet. Breastfeeding mothers on a milk free diet require a calcium and vitamin D supplement (containing a minimum of 1000mg calcium and 10mcg vitamin D) follow local guidance.
- Both mother and infant require referral to a paediatric dietitian.
- If mothers do not wish to or are unable to follow a milk free diet an extensively hydrolysed formula may be prescribed for top up feeds.

Bottle fed infants:

- **Extensively hydrolysed formula (EHF)** should be the first line treatment if CMPA is suspected or diagnosed.
- **Amino acid formulas (AAF)** are indicated for those suffering with IgE mediated symptoms, an infant reacting to breast milk or symptoms that have not improved on EHF.
- It is normal for stools to change colour to green when using an EHF or AAF.
- The taste of hydrolysed formula is unpleasant and it has a bitter smell. To improve compliance for infants **under 6 months** of age:
    - Use a bottle.
    - Mix small quantities into standard formula until the prescribed formula is accepted.
- To improve compliance for infants **over 6 months** of age:
    - Use a bottle, closed cup or straw.
    - Gradually introduce 1oz at a time of specialist formula mixed with current standard formula.

Soya formula:

- Soya formula is **not** recommended in infants under 6 months of age due to the high phytoestrogen content and possible cross reactivity (up to 50% of infants with non-IgE mediated allergy).
- If the child presents with a suspected CMPA over 1 year of age and there are no growth concerns, Alpro Growing up 1-3 yrs+ soya milk can be purchased in most supermarkets.

Prescribing criteria	Age range	Recommended formula	Clinical Indications
FIRST LINE EHF	Birth to 2 years	**<u>1st line primary care</u>** **Similac Alimentum** (Abbott Nutrition) *Casein based* *Lactose free*	Suspected or diagnosed cow's milk protein allergy.
SECOND LINE EHF	Birth to 2 years	**Althera** (SMA Nutrition) *Whey based* *Contains lactose*	Second line started if first line not accepted due to taste. Other EHF's are available, only issue if there is a clinical need determined by specialist or secondary care.
AMINO ACID Formulas Preferably started in specialist or secondary care	Birth to 2 years	**<u>1st line primary care:</u>** **Alfamino** (SMA Nutrition) (h)(v) + If commenced in hospital use first line **+ Neocate LCP** (Nutricia) (h)(v) <u>OR</u> **Puramino** (Mead Johnson) (h)	Use if symptoms have not resolved on eHF. Do not use if EHF not accepted simply based on taste.
OVER THE COUNTER - NOT TO BE PRESCRIBED Soya infant formulas only	6 month to 1 year	**SMA Wysoy** (SMA Nutrition) (v)(h)	Soya formula should only be used <u>after</u> 6 months of age and if the first or second line EHF is not accepted due to taste.

<u>GP REVIEW CRITERIA:</u>

- An eHF can be prescribed until the age of 2 years, however, some children may tolerate a milk alternative over 1 year of age. Refer to the latest written correspondence from a Paediatric Dietitian for guidance.
- All patients prescribed these formulas require a regular review by a Paediatric Dietitian for advice on calcium intake, challenging with cow's milk using the milk ladder and other feeding issues relating to a restricted diet. See "Referral guide to Nutrition and Dietetic Services in Luton and South Bedfordshire" for more information.
- Neocate Junior, Neocate Active, and Neocate Advance are specialised products and should only be recommended by secondary/tertiary care. These products <u>should not</u> be prescribed in infants under age of 1 year.

Pre-term infants

DIAGNOSIS:

Infants born before 34 weeks gestation and/or weighing less than 2kg at birth are considered pre-term and may be discharged from hospital on a **pre-term formula**.

TREATMENT SUMMARY:

- Any infant discharged on these formulas will require growth monitoring (weight, length and head circumference) by the 0-19 team.

- Please note pre-term infants can occasionally be discharged on the liquid formulations (Nutriprem 2 or SMA Pro Gold Prem 2) from hospitals out of area. There are no clinical benefits to using liquid formulations.
- **Do not prescribe liquid formulations in the community** due to significant cost implications.

<table>
<tr><th>Prescribing criteria</th><th>Age range</th><th>Recommended formula</th></tr>
<tr><td rowspan="2">SECONDARY CARE
Formula that should only be started in secondary care.</td><td rowspan="2">Use up to 3 months corrected age* but can be prescribed up to 6 months corrected age*.</td><td>Nutriprem 2 powder
(Cow and Gate)</td></tr>
<tr><td>SMA Pro Gold Prem 2 powder
(SMA Nutrition)</td></tr>
<tr><td colspan="3">* Corrected age: Corrected age is the actual age minus the number of weeks premature.</td></tr>
</table>

GP REVIEW CRITERIA:

- Formula can be stopped 3- 6 months corrected age if there is excessive or rapid weight gain. If stopped under 6 months of age then vitamin supplementation should follow current department of health guidance (see pre-term documents and links)

- Once an infant is older than 6 months corrected age the pre-term formula should be stopped and parents advised to start a standard infant formula.

- If there are concerns regarding an infant's growth on return to standard formula, see "Referral guide to Nutrition and Dietetic Services in Luton and South Bedfordshire" for more information.

Faltering growth

DIAGNOSIS:

A weight, length and ideally head circumference are required for diagnosis. Faltering growth is defined by one of the following criteria:

- A weight of an infant falls below the bottom centile (0.4^{th})
- A downward fall through 2 or more centiles for weight or head circumference
- A difference of height and weight of more than two centiles

TREATMENT SUMMARY:

- It is important to consider the reason for faltering growth e.g. iron deficiency anaemia, GORD or a child protection issue and treat accordingly or refer to a paediatrician.
- In breast fed infants consider a referral to a breastfeeding advisor for assessment and support with expressed breast milk top ups.
- Consider a referral to the 0-19 team for behaviour management advice if infant is over 6 months old, eating solid food and exhibiting fussy eating behaviour.
- Before commencing a high energy formula ensure parents or carers are **offered advice on suitable high calorie foods if the infant is over 6 months old.** Contact your local food first team for electronic resources.
- When commencing a high energy formula please ensure the full recommended prescribed dose is issued and consumed every day to maximise energy intake for weight gain.
- All infants on a high energy formula will need regular growth monitoring from the health visiting team (weight, length or height and head circumference) to ensure catch up growth is achieved and appropriate discontinuation of formula to minimise excessive weight gain.

Prescribing criteria	Age range	Recommended formula
SECONDARY CARE High energy formula to be started in **secondary or specialist care.**	From birth to 18 months or 8 kg body weight.	**Infatrini** (Nutricia) (h)
		SMA Pro High Energy (SMA Nutrition)
		Similac High energy (Abbott Nutrition) (h)(v)

GP REVIEW CRITERIA:

- Clinical effectiveness of the supplements should be assessed by regular growth monitoring and assessment.
- Once catch up growth has been achieved the high energy formula should be stopped to prevent excess weight gain.
- If consuming full therapeutic dose and failing to gain or achieve expected growth, consider a referral to a Paediatrician for further investigation .

Supporting documents and website links

Cow's milk protein allergy:

- National Institute for Health and Care Excellence (2011) Clinical Guidelines 116: Food allergy in children and young people: Diagnosis and assessment of food allergy in children and young people in primary care and community settings. Available at: http://www.nice.org.uk/guidance/cg116

- Venter, C et al (2013) 'Diagnosis and management of non-IgE mediated cow's milk allergy in infancy – a UK primary care practical guide' Clinical and Translational Allergy. Available at: http://www.ctajournal.com/content/pdf/2045-7022-3-23.pdf (MAP guidelines)

- First steps to Nutrition Specialised Infant milk in the UK 0-6 months http://www.firststepsnutrition.org/pdfs/Specialised_infant_milks_March2017.pdf

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PRE-TERM:

- First steps to Nutrition Specialised Infant milk in the UK 0-6 months http://www.firststepsnutrition.org/pdfs/Specialised_infant_milks_March2017.pdf
- Bliss website: https://www.bliss.org.uk/
- Vitamin supplementation http://www.gpref.bedfordshire.nhs.uk/media/140546/feedingthepretermbaby.aug15.pdf

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FALTERING GROWTH:

- Contact your local food first team for age appropriate resources or refer to electronic resources on GP ref

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Health visiting team Essex Partnership University Hospital Trust.
Paediatricians Bedford Hospital Trust.

An assessment framework was used to compile details of infant formulae available at time of review and subsequent recommendations for the prescribing guidelines. This document is available upon request.

Date ratified by The Bedfordshire and Luton Joint Prescribing Committee: **20th September 2017**

Date for review: **September 2019.**

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8. Young, L et al (2012) 'Nutrient-enriched formula vs standard term formula for preterm infants following hospital discharge (review)' The Cochrane Library. Available at: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004696.pub4/pdf